

EPA-2023-001854 (Ison Natamycin FOIA)

Response Information

On January 23, 2023, requester Amanda Ison submitted to EPA the following FOIA request:

- A list of all crops intended for human consumption for which the substance "natamycin" (also known as Pimaricin) is approved for use on; a list of all crops intended for human consumption for which the above mentioned substance is pending approval for use on.
- A copy of all reports or documents generated in the process of the EPA's determination that the substance "natamycin" (also known as Pimaricin) is not harmful to human health, including reports and documents generated for document 2016-20409 and research done to meet the requirements of Section 408(c)(2)(A)(i) of FFDCA, the determination that this substance is exempt from the requirement for a tolerance due to the determination of the substance as "safe".

On March 21, 2023, EPA's Office of Chemical Safety and Pollution Prevention provided the following response to the FOIA request:

- Per 40 CFR 180.1315, DSM petitioned EPA to establish a tolerance exemption for natamycin, which eliminates the need to establish maximum permissible residue levels for natamycin pesticide use on certain crops. The tolerance exemption was first established on May 18, 2012, for natamycin use in or on mushrooms when applied as a Fungistat to prevent the germination of fungal spores on mushrooms produced in mushroom production facilities. On August 25, 2016, DSM submitted a petition to amend the tolerance exemption (40 CFR 180.1315) to encompass natamycin residues in or on pineapples, citrus, pome, stone fruit crop groups, avocado, kiwi, mango, and pomegranates when used in accordance with label directions and good agricultural practices. This regulation eliminated the need to establish a maximum permissible level for residues of natamycin on the following foods: in or on mushrooms, pineapples, citrus, pome, stone fruit crop groups, avocado, kiwi, mango, and pomegranate when used in accordance with label directions.
- All information used to establish the tolerance exemption is available in the public docket, and can be found at <https://www.regulations.gov> at docket number EPA-HQ-OPP-2010-0727 (2012 mushroom tolerance exemption) and EPA-HQ-OPP-2015-0811 (2016 amendment that added pineapples, citrus, pome, stone fruit crop groups, avocado, kiwi, mango and pomegranate). All of the crops for which natamycin is allowed to have residues on are listed in the tolerance exemption (e.g., <https://www.federalregister.gov/documents/2016/08/25/2016-20409/natamycin-exemption-from-the-requirement-of-a-tolerance>). Please note that DSM has submitted a petition to amend the tolerance to include seed treatments, which is something that EPA announced in a public docket.